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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

TH

Office Action Summary	Application No.	Applicant(s)	
	10/792,273	YU ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2006 and 16 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 31-55* is/are pending in the application.

4a) Of the above claim(s) *5-28 and 35-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,29 and 31-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/28/04 & 11/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-29 and 31-55 are presented for examination.

Claim 30 is cancelled pursuant to the amendment dated November 27, 2006.

The Examiner acknowledges Applicant's Petition to make the instant application special filed July 6, 2006 and granted October 10, 2006 pursuant to MPEP §708.02(IV).

Acknowledgement is made of Applicant's claim for priority under 35 U.S.C. 119(e) to U.S. Provisional Patent Application No. 60/452,557, filed March 7, 2003.

Applicant's Information Disclosure Statements (IDS) filed June 28, 2004 (one page) and November 10, 2004 (one page) have each been received and entered into the present application. As reflected by the attached, completed copies of form PTO/SB/08A (two pages total), the Examiner has considered the cited references.

Applicant's response filed November 27, 2006 in response to the requirement for restriction/election dated October 25, 2006 has been received and entered into the present application. Applicant's subsequent response filed April 16, 2007 in response to the notice of non-compliant amendment dated December 14, 2006 has also been received and entered into the present application.

Requirement for Restriction/Election

Applicant's election **with traverse** of the invention of Group I (claims 2-4), directed to a composition comprising an alkaline pharmaceutical drug and an alkyl alpha hydroxyacid, and the election **with traverse** of the species of glycolic acid as the alkyl alpha hydroxyacid for examination, in the reply filed November 27, 2006 is acknowledged. Applicant's subsequent election of the species of terbinafine as the alkaline pharmaceutical drug for examination on the merits in the reply filed April 16, 2007 is also acknowledged. Furthermore, Applicant's omission of an election of additional agent from claims 35 or 36 is understood to be an election of composition wherein an additional agent is **not** present.

Insofar as Applicant has failed to particularly point out the supposed errors in the requirement for election of alkaline pharmaceutical drug, Applicant's election of the same has been herein treated as an election **without traverse**. Please reference MPEP §818.03(a).

Applicant traverses the restriction requirement between the inventions designates as Groups I-XI, stating that the previous Office Action fails to set forth how each group is separate and distinct from the remaining groups. Applicant asserts that the allegation that the compositions of these groups are chemically and structurally distinct from one another such that the active agents required to form each of the composition of each of the groups are distinctly different from one another is incorrect, and relies upon the instant specification (see, e.g., page 9, paragraph [0024]) to allege that features of the active agents that form the molecular complex are the same for each of the acids, lactones, etc. recited in the claims of Groups I-XI. Applicant further traverses the election requirement, stating that the claimed compounds all share a common structural feature that contributes to the formation of a molecular complex with an alkaline pharmaceutical drug.

Applicant's traversal has been carefully considered in its entirety, but fails to be persuasive.

Applicant's argument that the formation of the molecular complex is a characteristic shared by each of the groups designated as Inventions I-XI fails to be persuasive of error in the propriety of the present requirement for restriction. Though Applicant relies upon the fact that the claimed "molecular complex" is similar among each of the groups, regardless of whether it is an acid, lactone, etc., it remains that the structural formation of the complex with differ depending on the chemical structure of the acid or lactone form of the acid. For example, Applicant's claimed molecular complex is defined by dipole-dipole interactions or dipole-ionic interactions or ionic-ionic interactions. Accordingly, the type of interaction by which the molecular complex will be formed is directly dependent upon the structure of the alkaline drug and the acid or lactone form of the acid with which it is combined and which moieties are available to engage in dipole or ionic interactions. In other words, the variation in the chemical structure

of the active agents will clearly dictate how the two agents interact to form the molecular complex, and, thus, the interaction of a particular combination of agents may not be identical to, nor suggest or render obvious, another distinct combination of agents. As a result, in the absence of any showing that the claimed acids or alkaline drugs are obvious variants of one another and, thus, do not constitute distinct and/or independent inventions, the restriction requirement remains proper.

Applicant is further reminded that claim 1, for example, has been identified as a linking claim. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions will be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will then be entitled to examination in the instant application.

Further, Applicant is directed to the paragraph bridging pages 6-7 of the previous Office Action dated October 25, 2006 as to why the species of, e.g., acidic agent, are independent or distinct. Applicant is reminded that the election of species requirement was set forth for examination purposes due to the burdensome number of acidic agents claimed and the fact that the discovery of one such agent would not necessarily teach, suggest or render obvious any one or more of the other species. Applicant is again notified that, should the elected species be found allowable, search and examination will be expanded to other claimed species of acidic alkyl alpha hydroxyacid.

Accordingly, for the reasons set forth *supra* and those made of record at pages 2-12 of the previous Office Action dated October 25, 2006, the requirement for restriction/election remains proper and is made **FINAL**.

Claims 5-28 and 35-55 are **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b) as being drawn to non-elected subject matter.

The claims corresponding to the elected subject matter are claims 1-4, 29 and 31-34 and such claims are herein acted on the merits.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, it is noted that present claim 4 recites the limitation "2-hydroxyethanoic acid (glycolic acid)". The recitation of the parenthetical limitation renders the scope of the claims indefinite because Applicant has failed to delineate how such a limitation is intended to limit the claim. Though the limitation provided in the parentheses may be intended to circumscribe an additional or equivalent name for the same compound, it is unclear whether the parenthetical recitation of these terms is intended to simply make reference to another known name for the same compound or whether such a limitation is intended to limit the claim in another manner. In other words, the limiting effect of the claimed parenthetical limitation is not clearly set forth in the claims and, thus, fails to reasonably apprise one of ordinary skill in the art of the metes and bounds of the subject matter for which Applicant is seeking protection.

For these reasons, the claim fails to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and, thus, is properly rejected.

Claims 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 33 is directed to a composition comprising a molecular complex formed between an alkaline pharmaceutical drug and an alkyl alpha hydroxyacid, i.e., glycolic acid, wherein the molecular weight of the hydroxyacid is within the range of from about 50 to about 1000. Present claim 34 is also directed to a composition comprising a molecular complex formed between an alkaline pharmaceutical

drug and an alkyl alpha hydroxyacid, i.e., glycolic acid, wherein the molecular weight of the hydroxyacid is within the range of from about 70 to about 700.

In particular, it is noted that both claims 33 and 34 fail to define the units of the molecular weight of the hydroxyacid. For example, it is unclear whether Applicant intends for the molecular weight to be measured in grams, milligrams, or any other various unit of measure. As a result, Applicant has failed to reasonably apprise the skilled artisan of the metes and bounds of the subject matter for which he is seeking protection.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

For the purposes of examination and the application of prior art, present claims 33 and 34 will be interpreted to read upon molecular weights measured in grams.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willcox et al. (U.S. Patent No. 5,863,544; 1999) in view of STN Registry File Registry No. 79-14-1 ("Glycolic Acid").

Willcox et al. teaches cosmetic/dermatological compositions comprising from 10-30% by weight hydroxyacids, of which glycolic acid is a preferred acid (col.2, l.32-34), a silicone substituent and a coemulsifying compound, and an additional dermatologically active agent, such as, e.g., an antifungal, such as terbinafine (col.5, l.9-30). Willcox et al. discloses that the concentration of the active agent in any particular composition will depend on the nature of the active agent and the intended therapeutic effect, but will generally range from 0.001-10% by weight of the composition (col.5, l.44-47). Willcox et al. further discloses that the amount of hydroxyacid advantageously ranges from 12-38% by weight relative to the total weight of the composition.

STN Registry File Registry No. 79-14-1 is cited for its teaching of the molecular formula of glycolic acid, i.e., C2H4O3, which is equivalent to a molecular weight of 76 grams/mole and clearly meets Applicant's claimed limitations of present claims 33-34 (i.e., that the hydroxyacid has a molecular weight of from about 50-1000 or 70-700).

Regarding the formation of the claimed molecular complex (see, e.g., claim 1), whatever complex that is formed between two such agents when combined must necessarily be present in the prior art product of Willcox et al., absent factual evidence to the contrary, because the disclosed product of Willcox et al. meets each and every physical limitation of the instantly claimed product. Applicant is reminded that products of identical chemical composition cannot have mutually exclusive properties. Please reference MPEP at §§2112.01(I) and 2113, which states:

"Where the claimed and prior art products are identical or substantially identical in structure or composition...a *prima facie* case of either anticipation or obviousness has been established...When the PTO shows a sound basis for believing that the products of the Applicant and the prior art are the same,

the Applicant has the burden of showing that they are not." (MPEP §2112.01(I)) "Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, *the burden shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.*" (MPEP §2113; emphasis added)

Regarding the ratio(s) of alkaline pharmaceutical drug to the hydroxyacid (i.e., glycolic acid) as claimed in present claims 31 (i.e., from about 1:0.1 to about 1:40) or 32 (i.e., from about 1:0.5 to about 1:5), Willcox et al. teaches amounts of the glycolic acid in amounts of 10-30% by weight of the total weight of the composition and amounts of the active terbinafine antifungal agent in amounts of 0.001-10% by weight of the total weight of the composition. Accordingly, Willcox et al. clearly teaches ratios of active agent to hydroxyacid in an amount of, for example, 1:1.0 (10% active agent to 10% hydroxyacid) or 1:3.0 (10% active agent to 30% hydroxyacid) up to 1:10,000 (0.001% active agent to 10% hydroxyacid) or 1:30,000 (0.001% active agent to 30% hydroxyacid), which clearly overlaps Applicant's claimed ratio(s).

Furthermore, it is noted that the determination of the optimum ratios of the presently claimed active agents would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized, whether the compound is administered as part of a drug combination and the regimen of administration. Thus, the amounts and ratios that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific range of ratios are not seen to be inconsistent with those that would have been determined by the skilled artisan.

In addition, the concentrations and, thus, ratios, of the active ingredients are result-effective variables, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum or workable ranges would have been well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s). As taught by the MPEP at §2144.05, "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Non-Provisional Rejections

Claims 1-4, 29 and 31-34 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over, alternatively, claims 28, 35-37 and 41-42 of U.S. Patent No. 5,665,776, or claims 1, 3, 5 and 9 of U.S. Patent No. 5,702,688, or claims 1-4, 38-41 and 51-52 of U.S. Patent No. 5,877,212, each in view of Cole et al. ("A Comparison of a New Oral Antifungal, Terbinafine,

With Griseofulvin as Therapy for Tinea Corporis", *Arch Dermatol*, 1989 Nov; 125(11):1537-1539; Abstract Only).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the cited patents are not considered patentably distinct from each other because the pending claims are obvious over the patented claims.

The patented claims of the '776 patent, the '688 patent or the '212 patent each clearly provide for compositions of matter comprising, as active components of the composition, an alkyl alpha hydroxyacid, i.e., glycolic acid (also known as 2-hydroxyethanoic acid, see claim 5 of the '688 patent or claim 4 of the '212 patent; also known as 2-hydroxyacetic acid, see claim 42 of the '776 patent), and a variety of active dermatologic agents, such as various antifungal agents, e.g., griseofulvin.

Though the instant claims are directed to the use of terbinafine as the active dermatologic agent, one of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to use terbinafine in place of the griseofulvin compound of the patented claims because Cole et al. teaches that comparative studies of terbinafine and griseofulvin showed greater therapeutic efficacy of terbinafine in treating particular dermatologic conditions than griseofulvin for the same indication (see abstract). Such a person would have been motivated to do so because of a desire to enhance the therapeutic benefit to the patient and to enhance the activity and efficacy of the composition in treating the dermatologic condition.

Furthermore, though the instant claims recite the formation of a molecular complex between the terbinafine active agent and the glycolic acid component (see, e.g., claim 1), the fact that the patented claims clearly provide for compositions in which both the active dermatologic compound and the glycolic

acid component are directly combined with one another is obvious evidence that the molecular complex formed between two such agents when combined must necessarily be present in each of the patented products, absent factual evidence to the contrary, since products of identical chemical composition cannot have mutually exclusive properties.

Regarding the intended uses of the composition as recited in claim 9 of the '688 patent, though the instant claims do not expressly teach the treatment of the various dermatological disorders as claimed in claim 9 of the '688 patent, such limitations of the patented claims are intended uses of the composition and fail to impart any physical or material property to the combination of agents that would not have already been present in the patented product. As directed by the MPEP, as long as the product taught or suggested by the instant claims meets each and every physical and structural limitation and would also have been fully capable of performing the intended use as claimed in the patent, then the claims are properly rejected.

Please see MPEP §2111.02[R-3], which states, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim)...During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a

structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim...If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997)."

Lastly, regarding the claimed amounts of claims 38-41 of the '212 patent, it is noted that the determination of the optimum dosage amounts or ratios of the active ingredients is generally considered a matter well within the purview of, and *prima facie* obvious to, one of ordinary skill in the art at the time of the invention. Such a determination would have been made in accordance with a variety of factors, including but not limited to, the dosage to be administered, the frequency of administration, the desired therapeutic effect and patient compliance with the regimen. Thus, the amounts and, thus, the ratios, that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the patented specific amounts of the active agents are not seen to be inconsistent with those that would have been determined by the skilled artisan in the instant application.

Accordingly, rejection of claims 1-4, 29 and 31-34 is proper over, alternatively, claims 28, 35-37 and 41-42 of U.S. Patent No. 5,665,776, or claims 1, 3, 5 and 9 of U.S. Patent No. 5,702,688, or claims 1-4, 38-41 and 51-52 of U.S. Patent No. 5,877,212 as claiming obvious and unpatentable variants thereof.

Provisional Rejection

Claims 1-4, 29, 31 and 33 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 29-31 of U.S. Patent Application No. 11/050,434 in view of Davis et al. ("Terbinafine. A Pharmacoeconomic Evaluation of Its Use in Superficial Fungal Infections", *Pharmacoeconomics*, 1995 Sep; 8(3):253-269; Abstract Only).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims

because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending application are not considered patentably distinct from each other because the instant claims are obvious over the copending claims.

The copending claims clearly provide for compositions comprising a molecular complex formed between various alkaline pharmaceutical drugs, such as, e.g., itraconazole, and a hydroxyacid compound, such as, e.g., glycolic acid, wherein the hydroxyacid has a molecular weight of from about 50-1000 and the molar ratio of the alkaline pharmaceutical drug to the hydroxyacid is from about 1:0.1 to about 1:40.

Though the copending claims do not expressly recite the use of terbinafine as the alkaline pharmaceutical drug in the claimed composition, one of ordinary one skill in the art at the time of the invention would have found it *prima facie* obvious to use terbinafine in place of, for example, the itraconazole compound of the copending claims because Davis et al. teaches that terbinafine is fungicidal *in vitro* and demonstrated improved pharmacokinetic properties with respect to drug penetration into the nail tissue following oral administration and greater cost-effectiveness when compared to other common antifungals, such as, e.g., itraconazole (abstract). Such a person would have been motivated to do so because of a desire to enhance the therapeutic benefit to the patient for the treatment of superficial fungal infections with greater cost-effectiveness and to enhance the activity and efficacy of the composition.

Accordingly, rejection of claims 1-4, 29, 31 and 33 is proper over claims 1-4 and 29-31 of U.S. Patent Application No. 11/050,434 as claiming obvious and unpatentable variants thereof. This is a provisional rejection because the copending claims have not, in fact, been patented.

Conclusion

Rejection of claims 1-4, 29 and 31-34 is proper.

Claims 5-28 and 35-55 are **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

May 13, 2007

5/14/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER